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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,472	03/26/2001	Wilson Smart	Kum11Sil.Prb	6422

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Kumetrix Inc.
29524 Union City Blvd.
Union City, CA 94587

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,472

Applicant(s)

SMART ET AL.

Examiner

Robert L. Nasser Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 31, 34, 36-50, 57, 58, 60, 64, 65, 67-70 is/are pending in the application.
- 4a) Of the above claim(s) 28-30 and 38-47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 48-50 and 58 is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-27, 31, 34, 36, 37, 57, 64, 65, 67-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 28-30 and 38-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57, 64, and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the range as recited in these claims. Essentially, applicant is introducing a new range, i.e. 50-100% having a uniform thickness. This does not have support and accordingly it constitutes new matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10, 12, 25-27, 31, 34, 36-37, 50, 60, 67, 68, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al WO 01/93930 in view of Pisano et al 5928207. Frazier et al shows a microneedle having a silicon substrate

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(see page 8, line 10) and has a body portion 18 and a penetration portion 11, with a biosensor 17 mounted on the penetration portion. It does not state whether the silicon is single crystal silicon. Pisano is one of several references that teach that it is well known to manufacture microneedles from single crystal silicon (see columns 7 and 8, example 1). Hence, it would have been obvious to modify Frazier et al to use single crystal silicon, as it is merely the selection of a well-known silicon for the identical purpose. The examiner notes that when the device is not used, no portion penetrates into the body. As such, there is no closed flow path on a portion that penetrates into the body. With respect to claims 2-4, the penetration portion end tapers from the body to a tip at the penetration end, where the taper is uniform in the X direction. With respect to claims 5-8 and 60, the substrate has the recited dimensions (see columns 9 and 10). Claim 10 is rejected in that the point is a symmetrically shaped point. Claim 12 is rejected in that there is structure discussed in column 7, lines 21-26 for interfacing with an analyte meter and there is a signal carrier between the sensor and the interface. Claim 25 is rejected in that the sensor is optical. Claim 26 is rejected in that the sensor is spaced enough from the body portion to penetrate into the body. Claim 27 is rejected in that the sensor is "near" the penetration end. Claim 31 is rejected in that the biosensor is on a planar surface of the substrate. Claims 34 and 36 are rejected in that there are multiple biosensors and different x dimension depths. Claim 37 is rejected in that the substrate is single crystal silicon. Claim 50 is rejected in the, in addition to the reasons given above, there are multiple biosensors sensing multiple parameters. Claim 68 is rejected in that the silicon dioxide layer of Pisano is a "cover."

Claims 9, 13-15, 18, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Pisano et al, as applied to claims 1-8, 10, 12, 25-27, 31, 32, 34, 36-37, 50, and 60 above, further in view of Say et al 6134461. With respect to claim 9, Say et al shows a chisel shaped microneedle. Therefore, it would have been obvious to modify Frazier et al to use the needle shape taught by Say et al, as it is merely the substitution of one known equivalent needle shape for another. With respect to claim 13, Frazier does not teach how the device is attached to the external device. Say et al shows a similar analyte monitoring device where the microneedle device is attached to the external device with contact pads 49. Hence, it would have been obvious to modify the above combination to use such an attachment technique, as it is merely the selection of a well known attachment technique in the art. With respect to claims 14 and 15, Frazier uses an electrochemical sensor to measure analyte levels. Claim 18 is rejected in that the microneedle of Pisano has an electrically insulation silicon dioxide layer 92 on the substrate. Claim 19 is rejected in that it is an silicon dioxide film. Claims 21-24 are rejected in that applicant has admitted that the techniques recited are well known techniques used to deposit contacts on a substrate and therefore it would have been obvious to modify the above combination et al to use the recited techniques.

Claims 1-10, 12-15, 18, 19, 20-27, 31, 34, 36-37, 50, 60, and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al WO 01/93930 in view of Pisano et al 5928207 and Say 6134461. Frazier et al shows a microneedle having a silicon substrate (see page 8, line 10) and has a body portion 18 and a penetration

portion 11, with a biosensor 17 mounted on the penetration portion. It does not state whether the silicon is single crystal silicon. Pisano is one of several references that teach that it is well known to manufacture microneedles from single crystal silicon (see columns 7 and 8, example 1). Hence, it would have been obvious to modify Frazier et al to use single crystal silicon, as it is merely the selection of a well-known silicon for the identical purpose. Say further teaches a device where the sensor is at the penetration end and is connected to the body portion via wires. As such, there is no closed channel. Therefore, it would have been obvious to modify the above combination to use such a structure, as it is merely the substitution of one known equivalent configuration for another. With respect to claims 2-4, the penetration portion end tapers from the body to a tip at the penetration end, where the taper is uniform in the X direction. With respect to claims 5-8 and 60, the substrate has the recited dimensions (see columns 9 and 10). 10, 12, 25-27, 31, 32, 34, 36-37, 50, and 60 above, further in view of Say et al 6134461. With respect to claim 9, Say et al shows a chisel shaped microneedle. Therefore, it would have been obvious to modify Frazier et al to use the needle shape taught by Say et al, as it is merely the substitution of one known equivalent needle shape for another. Claim 10 is rejected in that the point is a symmetrically shaped point. Claim 12 is rejected in that there is structure discussed in column 7, lines 21-26 for interfacing with an analyte meter and there is a signal carrier between the sensor and the interface. With respect to claim 13, Frazier does not teach how the device is attached to the external device. Say et al shows a similar analyte monitoring device where the microneedle device is attached to the external device with contact pads 49.

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Hence, it would have been obvious to modify the above combination to use such an attachment technique, as it is merely the selection of a well known attachment technique in the art. Claim 18 is rejected in that the microneedle of Pisano has an electrically insulation silicon dioxide layer 92 on the substrate. Claim 19 is rejected in that it is an silicon dioxide film. Claims 21-24 are rejected in that applicant has admitted that the techniques recited are well known techniques used to deposit contacts on a substrate and therefore it would have been obvious to modify the above combination et al to use the recited techniques. Claim 25 is rejected in that the sensor is optical. Claim 26 is rejected in that the sensor is spaced enough from the body portion to penetrate into the body. Claim 27 is rejected in that the sensor is "near" the penetration end. Claim 31 is rejected in that the biosensor is on a planar surface of the substrate. Claims 34 and 36 are rejected in that there are multiple biosensors and different x dimension depths. Claim 37 is rejected in that the substrate is single crystal silicon. Claim 50 is rejected in the, in addition to the reasons given above, there are multiple biosensors sensing multiple parameters. Claim 69 is rejected as discussed above. Claims 69-70 are met by incorporating the structure of Say.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Pisano et al and Say et al, as applied above, further in view of in view of Meade et al 5770369. Meade teaches that electrogravimetric sensors and electrochemical sensors are equivalent for analyte monitoring. Hence, it would have been obvious to modify the above combination to use an electrogravimetric sensor, as it is merely the substitution of one known equivalent for another.

Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Pisano et al and Say, as applied above, further in view of Lin et al 5855801. Lin et al shows electrical components on a silicon dioxide insulation layer of a microneedle. Hence, it would have been obvious to modify the above combination to use such an arrangement, as it is merely the substitution of one known equivalent arrangement for another.

Claims 57, 64, and 65 are rejected is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Pisano et al and Lin et al and Say et al. The Frazier/Pisano combination does not teach the relative thicknesses of the needle and body 18. Lin et al teaches that the body is thicker than the needle (see column 4, lines 21-35). Hence, it would have been obvious to modify the above combination to make the body thicker than the needle, as it is merely the substitution of one known equivalent configuration for another. In addition, Say teaches an alternate construction of a similar device that has a uniform thickness. As such, it would have been obvious to modify the above combination to have a uniform thickness, as it is merely the substitution of one known equivalent construction for another. With respect to claims 64 and 65, the dimensions are taught by Frazier on page 9.

Claims 11, 48-50 and 58 are allowable. Claim 11 defines over the art in that none of the art teaches the microfillet portion. In view of the discussion on page 12 of the specification, it is clear that the inclusion of such a portion is more than merely a change in shape and therefore defines over the art of record. Claims 48, 49, and 58 define over the art in that none of the art shows the biosensor in a cavity on the

substrate. Claim 50 defines over the art of record in that none of the art shows multiple biosensors on multiple sides of the substrate, as claimed.

Applicant's arguments filed 12/21/2005 have been fully considered but they are moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is 571 272-4731. The examiner can normally be reached on 9:30 - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RLN
March 14, 2006

Robert L. Nasser Jr.
ROBERT L. NASSER JR.
EXAMINER